Remarks

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Thus, claim 1 has been amended to incorporate the subject matter of claim 14, as a result of which claim 14 has been cancelled.

Substance of Interview

Applicants express their appreciation for the courtesy of a telephone interview granted to their attorney by Examiner Webb and Mr. Lundgren on January 26, 2010.

At the beginning of the interview, Applicants' attorney expressed a willingness to incorporate claim 14 into claim 1, in order to address the rejections of the claims under the first and second paragraphs of 35 U.S.C. §112. Mr. Lundgren appeared to indicate that this amendment would be effective to overcome these rejections.

During the interview, Applicants' attorney noted that the preparation of the present invention is in a sol state before use, and becomes transformed into a gel state after the preparation absorbs exudation in a wounded area of the skin, whereas in the Mizobuchi et al. reference relied upon by the Examiner in rejecting the claims, the preparation is already in a gel state prior to use since the polyacrylic acid (Table 4 of the reference specifically cited by the Examiner) in the preparation dissolves in the glycerin and is cross-linked by the aluminum magnesium metesilicate cross-linking agent in the preparation. This difference is reflected by the fact that Table 4 in the reference represents the "cataplasms" (column 6, line 45) of Examples of 21-27 which include Table 4, whereas the present invention is directed to an "ointment" (line 1 of claims 1 and 15). Applicants' attorney noted that even Mizobuchi et al. distinguish between the "ointments" (column 4, line 58) in Examples 1-7, and the "cataplasms" in Examples 21-27.

Mr. Lundgren indicated that the rejection will be reconsidered after the response is filed.

Patentability Arguments

Referring to the comments set forth above concerning the interview, it is the understanding of Applicants' attorney that the amendment to claim 1 will be effective to overcome the rejection of claims 1-2, 6-7, 13-14 and 16 under the first paragraph of 35 U.S.C. §112, as well as the rejection of claims 1-2, 6-7, 13 and 16 under the second paragraph of 35

U.S.C. §112. It is Applicants' position that the amendment to claim 1 renders these rejections moot.

The patentability of the presently claimed invention over the disclosures of the references relied upon by the Examiner in rejecting the claims, will be apparent upon consideration of the following remarks.

Thus, the rejection of claims 1-2; 6-7 and 13-16 under 35 U.S.C. §103(a) as being unpatentable over Mizobuchi et al. (WO '651/US '355) in view of Knutson (US '651) is respectfully traversed.

Referring to the comments set forth above concerning the telephone interview, the Mizobuchi et al. preparation is essentially different from the preparation of the present invention. The reference composition, including those in Table 4 referred to by the Examiner, form a cross-linked gel before use because the polyacrylic acid dissolves in the glycerin, etc. and reacts with the cross-linking agent to form a cross-linked gel, as a result of which the polymers in Examples 21-27 are no longer in a sol state. In contrast to this, the preparation of the present invention is in a sol state before use, because the water-soluble polymer (e.g. sodium polyacrylate) does not dissolve in a non-aqueous media (e.g. glycerin), therefore cannot form a gel even though the preparation contains a cross-linking agent; and then undergoes a phase transition to a gel after the preparation absorbs exudation in a wounded area of the skin. This is a fundamental difference between the preparation of the present invention and the Mizobuchi et al. preparation, and is reflected by the fact that the present claims are directed to an "ointment", whereas the Table 4 preparations of Mizobuchi et al. are "cataplasms". As noted during the interview, Applicants take the position that the term "ointment" in the present claims must be taken into consideration in determining the patentability of the invention over the prior art. Referring to MPEP 2111.02 (Effect of Preamble), any terminology in the preamble of a claim that limits the structure of the claimed invention must be treated as a claim limitation; and the determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application to gain an understanding of what the inventors actually invented and intended to encompass by the claims. Considering the present application as a whole, it is clear that the ointment preparation must be in a sol state before use, and is transformed to a gel state during/after use (for example, see page 6, lines 15-25; page 8, line 21 - page 9, line 16; and the abstract). Thus, the term "ointment" represents a structural limitation ("sol state before use"),

which distinguishes it from the structure of the Mizobuchi et al. preparations (cross-linked or gel state before use). The claim preamble is thus necessary to give life, meaning, and vitality to the claim, reference in this regard again being made to MPEP 2111.02.

As the Examiner points out in the Office Action, the composition disclosed in Mizobuchi et al. does not contain water, and also the moisture content of Applicants' ointment in claim 1 is 3% or less. In such a non-aqueous media, however, solubilities of polyacrylic acid and sodium polyacrylate are quite different. A cross-linking agent is included in the composition of Mizobuchi et al. and also in the present invention. But polyacrylic acid dissolves in multivalent alcohol such as glycerin, etc. (Mizobuchi et al., column 4, lines 25-27), whereas sodium polyacrylate dissolves little in it. Accordingly, polyacrylic acid dissolves in multivalent alcohol and reacts with a cross-linking agent to afford a gel (adhesive gel matrix) in the composition of Mizobuchi et al. (column 4, lines 28-30). In the ointment of the present invention, however, sodium polyacrylate does not dissolve in non-aqueous media (glycerin and propylene glycol) and therefore cannot form a gel even through a cross-linking agent is contained therein ([0047] lines 5-7).

The Examiner describes "sodium polyacrylate inherently forms a gel upon exposure to water", but a gel of sodium polyacrylate is not always simply applicable to the present invention.

One of characteristics of the external preparation of the present invention is "a superior property of being easily separated substantially as a mass after its use." As described in the specification [0030], the formed gel material, which the preparation of the present invention is transformed to after use, is advantageous in substantially a mass of gel material having a high strength, as compared with the conventional gel preparation.

In general, a gel preparation will not be removed as a mass and a patient will have to wash the wounded skin to completely remove the preparation after its use. Also, a gel preparation is usually so fragile that it is crushed in use to form a crushed gel type preparation, which cannot be removed as a mass and so on.

The preparation of the present invention is in sol state (uncross-linked state) before use ([0028, lines 3-4), and the preparation has sufficient exudation absorbability before and after gel formulation. These advantages are obtained by selecting or combining the ingredients of the present invention [0036]. Therefore the gel of sodium polyacrylate itself simply formed by exposure to water does not have the effective advantages described above.

As the Examiner also points out, Mizobuchi et al. disclose a composition comprising polyacrylic acid, glycerin, etc. and aluminium magnesium metesilicate (cross-linking agent) in Examples 21-27 (Table 4). Although the Examiner relies on Table 4 in this reference, Applicants note that there is no disclosure of sodium polyacrylate in Table 4, nor is there any particular suggestion which would lead one of ordinary skill in the art to include sodium polyacrylate in the preparations set forth in Table 4. However, even if the sodium polyacrylate may be added to the preparation, the polyacrylic acid dissolves in glycerin, etc. and reacts with the cross-linking agent to form a cross-linked gel in these examples, and the polymers of these examples are no longer in a sol state (column 4, line 25-30).

Thus, even if sodium polyacrylate is added to the preparation of Mizobuchi et al., a cross-linked gel is already formed and "phase transition to gel **after** the preparation absorbs exudation" (see present claim 1) does not occur. Therefore the preparation of Mizobuchi et al. does not have the effective advantages of the present invention as described above.

The present inventors selected sodium polyacrylate (claim 6), which does not dissolve in a non-aqueous media, to form a cross-linked gel after being applied to a wounded skin. Sodium polyacrylate disclosed in Mizobuchi et al. is used to prepare a **plaster** formulation containing water (column 3, lines 59-64). In the preparation, sodium polyacrylate already forms a cross-linked gel and "phase transition to gel **after** the preparation absorbs exudation" in a wounded area of the skin cannot occur.

The ointment disclosed in Knutson is a formulation containing water (column 2, lines 20-40). An objective in the present invention to form a cross-linked gel after absorbing exudation cannot be achieved in the aqueous ointment disclosed in Knutson.

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

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